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09/555,115	08/01/2000	Gregory I. Bohach	12136.1USWO	4351

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT

PAPER NUMBER


1645

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. <b>09/555,115</b>	Applicant(s) <b>Bohach</b>	
Examiner <b>Mark Navarro</b>	Art Unit <b>1645</b>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21, 24, and 25 is/are pending in the application.
- 4a) Of the above, claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-21, 24, and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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### **DETAILED ACTION**

1. The numbering of the claims is not accordance with 37 CFR 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CFR 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

This application currently does not contain a claim number 4. Therefore, claim numbers 5-26, have been renumbered as claims 4-25 respectively by Rule 1.126.

### ***Election/Restriction***

2. Applicant's election with traverse of Staphylococcal enterotoxin C1 in Paper No. 16, (received November 15, 2002) is acknowledged. The traversal is on the ground(s) that the group of modified toxins are closely related to one another and are not so unique as to comprise distinct inventions. Applicants further assert that they are all modified versions of disulfide loop containing bacterial pyrogenic toxins as discussed starting at page 5, line 12 of the specification.. This is not found persuasive. Applicants refer to the restriction as an election of species. However, Applicants are respectfully directed to the restriction requirement mailed December 19,

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2001, no election of species was mentioned or implied. The claims have been restricted based upon the unique primary, secondary, and tertiary structure of each of the recited modified toxins. As set forth in MPEP 803.04, biological molecules with separate sequences are structurally distinct chemical compounds and are unrelated to one another.

Consequently, claims 1-21 and 24-25 are pending in the instant application, of which claim 4 has been withdrawn from further consideration. The claims will be examined for their full generic breadth, however limitations to a specific toxin, other than Staphylococcal enterotoxin C1 are withdrawn from further consideration.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

3. Claim 25 is objected to because of the following informalities: Claim 25 is objected to for reciting an amino acid sequence without a corresponding SEQ ID NO: tag. Applicants are reminded that all sequences of 4 or more amino acids, and 10 or more nucleotides are required to have a corresponding SEQ ID NO: tag. For examination purposes SEQ ID NO: 66 has been searched for claim 26. Appropriate correction is required.

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*Claim Rejections - 35 USC § 112*

4. Claims 1-3, 5-21, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-3, 5-21 and 24-25 recite a modified pyrogenic toxin derived from a native disulfide loop-containing pyrogenic toxin, wherein the modified toxin comprises a disulfide loop region containing no more than 10 amino acid residues.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, a modified pyrogenic toxin comprising a disulfide loop region alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by modified toxins comprising a disulfide loop region which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

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Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

5. Claims 1, 19 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the use of the phrase "derived." Since it is unclear if the antigenic polypeptides are undergoing any kind of chemical modification as implied by the recitation of "derived." Since it is unclear how the antigenic polypeptides are to be derived as referred to in the claims, there is no way for the person of skill in the art to ascribe a discrete and identifiable definition to said phrase.

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6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of “substantially decreased toxicity.” One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance, at what point is activity “substantially” decreased, (90%, 50%, 2%, etc.)? Furthermore, at what point is the decrease “non-substantial?” Without a clear definition as to the metes and bounds of the term “substantially decreased” one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

7. Claims 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of “at least about 100-fold/40%.” One of skill in the art would be unable to determine the metes and bounds of the claimed invention. “At least” one thousand degrees in claim means minimum temperature of one thousand degrees “About” in claim allows some tolerance. *National Research Development Corp v. Great Lakes Carbon Corp.* (DC Del) 188 USPQ 327. Consequently, the term “at least about” confers two separate contradictory limitations.

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8. Claims 8, 10, 12, 14, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "amino acid position ##." One of skill in the art would be unable to determine the metes and bounds of the claimed limitations. First, the claims do not recite a sequence for a reference point, consequently any particular amino acid "number" is indefinite. Furthermore, the claims are drawn to a "modified toxin" is the number referring to the position in the wild type toxin or the newly created modified toxin? Furthermore, does the numbering take into account a signal sequence? Without a clear sequence as a reference, reference to a particular amino acid number is simply vague and indefinite.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 1-3, 5-21, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Olivers *et al.*



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The claims are drawn to a modified pyrogenic toxin derived from a native disulfide loop-containing pyrogenic toxin, wherein the modified toxin comprises a disulfide loop region containing no more than 10 amino acid residues.

Olivers *et al* (US Patent Number 5,885,780) disclose of methods for identifying and purifying small conotoxin like peptides. Olivers *et al* further set forth of purifying peptides of the formula Cys-Cys-Xaa-Xaa-Cys-Xaa-Xaa-Cys. (See abstract and SEQ ID NO: 15).

In view that the peptide disclosed by Olivers *et al* comprises a disulfide loop region containing no more than 10 amino acid residues, the disclosure of Olivers *et al* is deemed to anticipate the claimed invention.

Although the reference appears to disclose the same polypeptide claimed by applicants, the reference does not disclose the polypeptides produced from a Staphylococcal enterotoxin C1. However the purification or production of a product from a particular source does not impart novelty to a product when the product is taught by the prior art. This is particularly true when the properties of the product are not changed by the process in an unexpected manner.

See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

May 12, 2003